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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,764	09/27/2006	Carl Ralph Flannery	19003-002US1 AM101404	5330

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EXAMINER
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KOSSON, ROSANNE

ART UNIT	PAPER NUMBER
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1652

MAIL DATE	DELIVERY MODE
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01/08/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/567,764

Applicant(s)

FLANNERY ET AL.

Examiner

Rosanne Kosson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2007.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 11, 19-21 and 36-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1, 11, 19-21 and 36-58 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicants' election without traverse of Group I, claims 1 and 19-21, drawn to the polypeptide of SEQ ID NO:9, in the reply filed on November 30, 2007 is acknowledged. These claims will be examined to the extent that they read on the elected polypeptide and are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to non-elected inventions to the extent that they read on different polypeptides, there being no allowable generic or linking claim. As noted in Applicants' supplemental reply filed on December 26, 2007, because SEQ ID NO:9 is a fragment of SEQ ID NO:7, claim 11 to the extent that it reads on SEQ ID NO:7 will also be examined in this application. Claim 11 to the extent that it does not read on SEQ ID NO:7 is withdrawn as being drawn to non-elected inventions. Non-elected inventions will not be considered for rejoinder in this application.

Applicants' response to the restriction requirement was to add a large number of claims that are drawn to a number of different compositions. Upon consideration of the amended claims, it has been determined that further restriction is required so that one composition may be searched.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows.

a) Applicants must elect one type of molecule that is O-linked to SEQ ID NO:9:  $\beta$ -(1-3)-Gal-GalNac or keratin or chondroitin (see claims 19, 36 and 37). This election will be applied to claim 47.

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b) Applicants must elect one type of drug formulation: an injection or a capsule or a matrix (e.g., a slow-release formulation) (see claims 38-40). This election will be applied to claims 50-52.

c) Applicants must elect one second drug that is present in the composition: a local anaesthetic or a cytokine or a lymphokine or a thromolytic (sic) factor or an anti-thrombolytic factor or an anti-inflammatory agent (see claims 41-46). This election will be applied to claims 53-58.

Applicants are required, in reply to this action, to elect a single species in a), b) and c) above to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons. In part a) above, each derivative has a different molecule as a substituent, one disaccharide, one protein and one polysaccharide. Each of these substituents has different biological and chemical properties, a different structure, a different function and a different effect. In part b) above, each drug formulation has a different structure, different pharmacological properties, a different function and a different effect. In part c) above, each drug combination contains a different pair of drugs. Each second drug has a different structure, different pharmacological properties, a different function and a different effect and is used to treat a different group of diseases. Because the claimed species are not art-recognized equivalents, a holding of lack of unity of invention is proper.

**Applicants are advised that the reply to this requirement to be complete must**

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**include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).**

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rosanne Kosson  
Examiner, Art Unit 1652

rk/2007-12-28

*Rosanne Kosson*

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1652